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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,510	08/04/2003	Tadashi Okamoto	03500.015961.1	1267

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,510	OKAMOTO ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1. The preliminary amendments of 4 August 2003 are acknowledged and entered. The specification has been amended to introduce a first paragraph and claims 1-10 have been canceled.

Claims 11-14 are currently pending and under examination.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Methods for evaluating probe arrays.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite for the recitation "the labeling compound directly bonded to the substrate" because "labeling compound directly bonded" lacks proper antecedent basis in Claim 12.

Claim 13 is further indefinite for the recitation "the sequential synthesis without elongation reaction" because "without elongation" lacks proper antecedent basis in Claim 12.

Claim 13-14 are indefinite because the claims appear to require detection of the probe prior to the probe's production i.e. during a first step of the sequential synthesis. It is unclear how the probe is detected without first being synthesized. It is suggested the claim be amended to clarify.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Baier (U.S. Patent No. 6,245,518. filed 6 December 1999).

Regarding Claim 11, Baer discloses a method of measuring an amount of probe in an array comprising a plurality of immobilized probes at a plurality of sites (Fig. 1 and Column 3, lines 65-67) wherein the probes are sequentially synthesized at the sites (Column 5, lines 54-65 and Column 12, lines 30-42) wherein the probes are different from each other (e.g. all possible 6 mers, column 7, lines 41-61) wherein a labeling compound is coupled to each

terminus of the probe in the final synthesis step (Column 5, lines 56-60) and measuring an amount of labeling compound at each site (Column 15, lines 24-28 and Claim 1).

Regarding Claim 12, Baer discloses a method of evaluating an amount of target comprising reacting a probe array and target substance wherein the probe array comprises a plurality of immobilized probes at a plurality of sites (Fig. 1 and Column 3, lines 65-67) wherein the probes are sequentially synthesized at the sites (Column 5, lines 54-65 and Column 12, lines 30-42) wherein the probes are different from each other (e.g. all possible 6 mers, column 7, lines 41-61) wherein a labeling compound is coupled to each terminus of the probe in the final synthesis step (Column 5, lines 56-60), measuring an amount of labeling compound at each site to determine probe amount (Column 15, lines 24-28 and Claim 1) measuring an amount of target captured at each site Column 15, lines 28-41) and comparing the amount of probe to target substance (Column 4, lines 40-61 and Column 15, lines 42-50).

Regarding Claim 13, Baer discloses the method wherein the amount of label bound to the surface is compared to the probe label at each site (Column 15, lines 15-27). As stated above, it is unclear how the probe is detected prior to probe synthesis. However, Baer detects and compare the amount of probe to the amount of label bound to the substrate.

7. Claims 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by McGall et al (U.S. Patent No. 5,843,655, issued 1 December 1998).

Regarding Claim 11, McGall discloses a method of measuring an amount of probe in an array comprising a plurality of immobilized probes at a plurality of sites (Column 2, lines 4-34) wherein the probes are sequentially synthesized at the sites (Column 4, line 49-Column 5, line 10) wherein the probes are different from each other (Column 2, lines 35-47 and Column 11, lines 20-34) wherein a labeling compound is coupled to each terminus of the probe in the first

and in the final synthesis step (Column 6, lines 27-67) and measuring an amount of labeling compound at each site (Column 7, lines 25-34 and Column 9, lines 5-12).

Regarding Claim 12, McGall discloses a method of measuring an amount of probe in an array comprising a plurality of immobilized probes at a plurality of sites (Column 2, lines 4-34) wherein the probes are sequentially synthesized at the sites (Column 4, line 49-Column 5, line 10) wherein the probes are different from each other (Column 2, lines 35-47 and Column 11, lines 20-34) wherein a labeling compound is coupled to each terminus of the probe in the final synthesis step and measuring an amount of labeling compound at each site (Column 7, lines 25-34 and Column 9, lines 5-12) and measuring an amount of target captured at each site and comparing the amount of probe to target substance (column 13, lines 24-33).

Regarding Claim 13, McGall discloses the method wherein the amount of label bound to the surface is compared to the probe label at each site during a first coupling step (i.e. coupling efficiency, Column 6, line 27-Column 7, line 45). As stated above, it is unclear how the probe is detected prior to probe synthesis. However, McGall detects and compares the amount of coupling at each location on the substrate.

Regarding Claim 14, McGall discloses a method of measuring an amount of probe in an array comprising a plurality of immobilized probes at a plurality of sites (Column 2, lines 4-34) wherein the probes are sequentially synthesized at the sites (Column 4, line 49-Column 5, line 10) wherein the probes are different from each other (Column 2, lines 35-47 and Column 11, lines 20-34) wherein a labeling compound is coupled to each terminus of the probe in the first and in the final synthesis step (Column 6, lines 27-67) measuring an amount of labeling compound at each site during the first and subsequent coupling steps (Column 6, lines 27-67; Column 7, lines 25-34; and Column 9, lines 5-12) and measuring an amount of target captured at each site and comparing the amount of probe to target substance (Column 13, line 24-Column 14, line 11).

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
January 23, 2006